

inserting the proximal portion of the multi-lumen catheter tube into the area to be catheterized;

creating a subcutaneous tunnel having a first end and a second end, wherein the first end of the subcutaneous tunnel is near [the] said incision [near the area to be catheterized];

routing the distal portion of the catheter tube through the subcutaneous tunnel beginning at the first end and exiting through the second end of the subcutaneous tunnel; and

attaching the proximal portion of the hub body to the distal portion of the catheter tube.

REMARKS

Claims 1-15 are pending in the application.

Claims 7-13 are allowed.

Claims 1, 14 and 15 are rejected under 35 U.S.C. §103(a) as unpatentable over U.S. Patent No. 5,624,413 to Markel in view of U.S. Patent No. 4,692,141 to Mahurkar.

Claims 2-6 are objected to as being dependent upon a rejected base claim.

Applicant has amended Claim 1 so as to more distinctly claim the subject matter which the Applicant regards as the invention.

As to the 35 U.S.C. §103 obviousness rejections, Applicant respectfully traverses the rejections because the Office Action fails to establish a *prima facie* case of obviousness. There is no suggestion or motivation in the references for the modification

or combination. Absent such a suggestion or motivation in the primary reference for the modification or combination of references, such a modification or combination is improper.

The Examiner states, regarding the Markel et al. reference:

It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize Mahurkar's teaching into the invention of Markel et al. as such, in order to facilitate insertion of the multi-lumen catheter tube into the area to be catheterized, as taught by Mahurkar (Col. 3, ll. 35-37).

p. 3 of the Office Action.

The MPEP clearly states that if the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

The modification of the Markel patent suggested by the Examiner would clearly render the device of Markel unsatisfactory for its intended purpose. The Background of the Invention in the Markel patent discusses the various disadvantages of multi-lumen catheters and advantages afforded by assemblies of single lumen catheters, A.K.A. "Tesio catheters", concluding:

However, dual lumen catheters suffer from the same disadvantages as the Tesio double catheter assembly highlighted above in that one lumen cannot be replaced independently of the other lumen. Many dual lumen catheters also have poor flow characteristics due to the shape and size of the individual lumens.

Thus, there is a need in the art for a simple method of catheterization which requires only one procedure, which takes advantage of the benefits provided by Tesio [single lumen] catheters, and which does not

suffer from the shortcomings of the methods highlighted above. The present invention fills such a need.

Col. 2, lines 20-32. The Summary of the Invention states, in pertinent part:

The present method provides a method for inserting *a multiple catheter assembly* into an area of a body to be catheterized. The assembly comprises *a first and a second catheter*, each catheter having a distal portion and a proximal portion. . . . The first and second catheters are independently movable with respect to each other, or unattached to each other, along their entire length. The method includes the steps of . . . adjusting a longitudinal distance between the proximal portions of the first and second catheters to provide a predetermined longitudinal distance between the distal portions of the first and second catheters within the area . . .

Col. 2, lines 35-50 (emphasis added). Additionally, throughout the Detailed Description of the Preferred Embodiment the advantages of a multiple catheter Tesio-type assembly over a multi-lumen catheter are discussed repeatedly. For example Col. 6, lines 24-28 (the offset between the tips of the two catheters “d” is easily modified with two unconnected catheters); Col. 6, lines 53-57 (high flow rates collapse lumens in multi-lumen catheters which would not collapse in a single lumen catheter; higher flow rate equates to shorter procedure time for a patient); Col. 6, lines 62-67 (longer “d” and ability to independently move catheters help prevent recirculation of blood); and Col. 7, lines 14-29 (“important feature of the invention is that before, during and after insertion . . . first and second catheters 22, 24 are independently movable with respect to each other”; removal and replacement of one catheter can be performed independently and without interfering with other catheter).

The modification of Markel in the way suggested by the Examiner, i.e. substitution of a multi-lumen catheter for single lumen catheters, would necessarily



render the Markel patent unsatisfactory for its intended purposes. Thus, the Markel patent explicitly teaches away from multi-lumen catheters, stating very clearly the problems associated therewith and the advantages to be achieved by using independent single-lumen catheters. This being the case, there is no suggestion or motivation to make the proposed modification.

The Examiner also states that "Applicant's arguments filed 4/2/2003 have been fully considered but are moot in view of the new ground(s) of rejection". Applicant's respectfully disagree. The ground(s) presented in the Office Action of April 15, 2003 are essentially the same as those presented in the Office Action of October 15, 2002, i.e. that Markel et al. allegedly discloses all of the elements of claims 1, 14 and 15 except the use of a multi-lumen catheter in place of the single-lumen Tesio type catheters. The multi-lumen element is alleged to be provided by Bates in the October 15, 2002 Office Action and alleged to be provided by Mahurkar in the April 15, 2003 Office Action. This, however, does not deal with the arguments filed April 2, 2003. The argument presented is that Markel et al. cannot be combined with ANY reference where the proposed modification would render Markel unsatisfactory for its intended purpose. Whether it is contributed by Bates or by Mahurkar, the suggested modification of substituting a multi-lumen catheter into the disclosure of Markel would necessarily render Markel unsatisfactory for its intended purpose. Thus, there is still no suggestion or motivation to make the proposed modification, either by Markel in light of Bates or Markel in light of Mahurkar. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

Given the above reasons, the Applicant submits that a *prima facie* case of obviousness regarding claims 1, 14 or 15 cannot be presented utilizing the Markel patent in view of Mahurkar.

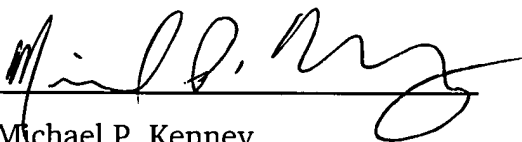
In view of the above amendment and remarks, reconsideration of the rejection and allowance of all claims is respectfully requested.

If an extension of time is required to enable this document to be timely filed and there is no separate Request for Extension of Time, this document is to be construed as also constituting a Request for Extension of Time Under 37 C.F.R. § 1.136(a) for a period of time sufficient to enable this document to be timely filed. Any fee required for such a Request for Extension of Time and any other fee required by this document pursuant to 37 C.F.R. §§ 1.16 and 1.17 and not submitted herewith should be charged to the Deposit Account of the undersigned attorneys, Account No. 01-1785; any refund should be credited to the same account. One copy of this document is enclosed.

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